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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,508	04/18/2001	Yun Lin	NEX 89	4609

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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/681,508

Applicant(s)

LIN ET AL.

Examiner

Stephanie Zitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited on the 1449 or on form PTO-892, they have not been considered.

Rejection under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) In claims 1-14 and 29, step c) lacks antecedent basis in step a) and step d) lacks antecedent basis in step c) because "capable of binding" is a property, not an action and step b) lacks antecedent basis in step a) because "exposing" in the latter step does not result in formation of the "complex" of step b). Method claims need not recite all operating details but should at least recite **positive, active steps** so that the claims will set out and circumscribe a particular area with a **reasonable degree of precision** and particularity and make clear what subject matter the claims encompass as well as make clear the subject matter from which others would be precluded. *Ex parte Erlich*, 3 USPQ2d 1011 at 6. It is suggested to use positive, active language in the claims.

(b) In claims 15-28, step d) lacks antecedent basis in step b) and step e) lacks antecedent basis in step d) because "capable of binding" is a property, not an action and step c) lacks antecedent basis in step b) because "exposing" in the latter step does not result in formation of the "complex" of step c). Method claims need not recite all operating details but should at least recite **positive, active steps** so that the claims will set out and circumscribe a particular area with a **reasonable degree of precision** and particularity and

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make clear what subject matter the claims encompass as well as make clear the subject matter from which others would be precluded. *Ex parte Erlich*, 3 USPQ2d 1011 at 6. It is suggested to use positive, active language in the claims.

(c) Claims 15-28 are confusing because the word "and" is missing from the penultimate line after "capture molecule" such that the capture molecule appears to be described as a reporter molecule. It is suggested to insert --and--.

(d) Claims 1-29 lack antecedent basis in prior steps for "said...complex(s)". It is suggested to recite formation of complexe(s) in appropriate preceding steps.

(e) Claims 1-29 lack antecedent basis in the preamble for the last step of "detecting said...complex" because the preamble recites "detecting the presence of a target compound". It is suggested to relate the last step to the preamble.

(f) Claims 1-29 are confusing in lacking antecedent basis for "said target molecule" in prior recitations of "target compound". It is suggested to observe consistency in wording for clarity and avoidance of lack of antecedence.

(g) Claims reciting "selected from X or Y" are confusing due to the improper Markush language. It is suggested to change "or" to --and--.

Rejections under 35 U.S.C. 102(b): Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 14-20 and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/41019. Regarding claims 1, 5, 14, 15 and 28, the claimed invention method comprising a) binding a target molecule in a substance to a capture molecule which is immobilized on a particulate solid support thereby forming a capture molecule:target molecule complex; b) removing unbound substance, i.e., washing; c) binding a reporter molecule to the target molecule thereby forming a capture molecule:target molecule:reporter molecule complex; d) detecting the complex by flow cytometry, wherein the capture molecule, reporter molecule or both are a nucleic acid ligand to the target molecule is

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disclosed at page 7, lines 1-13, page 13, lines 14-23, page 31, claim 13 and page 16, lines 13-14. The method of claim 15 is the same as that of claim 1 except wherein both the capture molecule and reporter molecule are nucleic acid ligands to the target compound and with the addition of steps for identifying a nucleic acid ligand to the target compound by the SELEX process. The former is disclosed at page 14, lines 4-6 and the latter at pages 8-9. Regarding claims 2-4 and 16-18, the fluoresceinated nucleic acid ligand detection system is disclosed at page 16, line 11. Regarding claims 6, 7 and 20, the protein target molecule is disclosed as L-selectin at page 22, line 6. Regarding claims 8 and 22, the method wherein the capture and reporter molecules are nucleic acid ligands is disclosed at page 14, lines 4-6. Regarding claims 12, 13, 26 and 27, the method wherein the substance is a biological fluid which may be selected from plasma or urine is disclosed at page 4, lines 23-24.

4. Claims 1-3, 6, 8, 12, 13, 15-18, 20, 22, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/40991. Regarding claims 1, 8, 15 and 22 the claimed invention method comprising a) binding a target molecule in a substance to a capture molecule which is immobilized on a solid support thereby forming a capture molecule:target molecule complex; b) removing unbound substance; c) binding a reporter molecule to the target molecule thereby forming a capture molecule:target molecule:reporter molecule complex; d) detecting the complexes, wherein the capture molecule, reporter molecule or both are a nucleic acid ligand to the target molecule is disclosed at page 24, claim 5. The method of claim 15 is the same as that of claim 1 with the addition of steps for identifying a nucleic acid ligand to the target compound by the SELEX process. The latter is disclosed at page 25-26, claim 13. Regarding claims 2-4 and 16-18, the reporter molecule is disclosed as a detection system which is a nucleic acid ligand labeled with a fluorophore at page 12, lines 15-20 wherein the latter is fluorescein at page 10, lines 22-23. Regarding claim 6 and 20, the protein target molecule is disclosed at page 24, claim 6. Regarding claims 12, 13, 26 and 27, the method wherein the substance is a biological fluid which may be plasma or urine is disclosed at page 13, lines 12-13.

Rejections under 35 U.S.C. 102(e): Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-6, 8-13, 15-20, 22-27 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by the patent to Gold et al. (6,242,246). The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Regarding claims 1 and 15, the claimed invention method comprising a) binding a target molecule in a substance to a capture molecule which is immobilized on a solid support thereby forming a capture molecule:target molecule complex; b) removing unbound substance; c) binding a reporter molecule to the target molecule thereby forming a capture molecule:target molecule:reporter molecule complex; d) detecting the complexes, wherein the capture molecule, reporter molecule or both are a nucleic acid ligand to the target molecule is disclosed at column 10, lines 41-47 and 63-66. The method of claim 15 is the same as that of claim 1 except wherein both the capture molecule and reporter molecule are nucleic acid ligands to the target compound and with the addition of steps for identifying a nucleic acid ligand to the target compound by the SELEX process. The latter is disclosed at column 1, lines 34-49. Regarding claims 2-4 and 16-18, the reporter molecule is disclosed as a detection system which is a nucleic acid ligand labeled with a fluorophore which is fluorescein at column 10, lines 62-67; column 11, line 48. Regarding claims 5 and 19, the solid support is disclosed as a membrane at column 9, lines 3-7. Regarding claims 6, 8-11, 20 and 22-25, the claimed method is

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disclosed at column 10 wherein the target molecule is a protein (line 34); wherein the capture and reporter molecules are nucleic acid ligands that bind to non-overlapping sites in the target molecule (lines 62-66); wherein the capture molecule is a nucleic acid ligand and the reporter molecule is a protein (lines 44-47); and wherein the reporter binds to a site on the capture molecule:target molecule complex (lines 34-68; column 11 at B.). Regarding claims 7 and 21 wherein the target protein is thrombin is disclosed at column 7, lines 52-59. Regarding claims 12, 13, 26 and 27, the method wherein the substance is a biological fluid which may be plasma or urine is disclosed at column 6 at 7. Regarding claim 29, the method is the same as that of claim 1 except that the presence of two or more target compounds is detected. This method is disclosed at column 2, lines 39-42, column 6 at 8. and column 8, lines 41-46.

6. Claims 1, 5, 6, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by the patent application publication of Dodge et al. (2002/0051974). The filing date of the Dodge et al. application is November 24, 1999. Regarding claim 1, the claimed invention method comprising a) binding a target molecule in a substance to a capture molecule which is immobilized on a solid support thereby forming a capture molecule:target molecule complex; b) removing unbound substance; c) binding a reporter molecule to the target molecule thereby forming a capture molecule:target molecule:reporter molecule complex; d) detecting the complexes, wherein the capture molecule, reporter molecule or both are a nucleic acid ligand to the target molecule is disclosed at page 26, claims 1, 2, 4 and 6. Regarding claim 5, the solid support is disclosed as a microsphere particle or membrane at page 8, paragraph [0062]. Regarding claim 6, the target molecule is disclosed as a protein at page 26, claim 9. Regarding claims 12 and 13, the substance is disclosed as a biological fluid which may be blood or urine at page 26, claim 11.

Prior art of interest

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent to Li, 6,180,348, discloses a variant SELEX method employing candidate mixtures and targets attached to magnetic beads.

Conclusion

8. No claim is allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.



Stephanie Zitomer, Ph.D.

May 3, 2002

